K021500

December 11, 2002

DEC 2 0 2002

510(K) SUMMARY: V.A.C.

I. Name of Device: **V.A.C.®** (Vacuum Assisted Closure™)

II. Classification Name: **Powered Suction Pump**
21 CFR 878.4780

III. 510(k) Applicant:

Kinetic Concepts, Inc. (KCI)
8023 Vantage Drive
San Antonio, TX 78265-8508
Contact: Judith Harbour 1-800-275-4524

IV. Substantial Equivalence: **V.A.C.**
510(k) No.K945062
V.A.C. PLUS
510(k) No.K992448

V. Description of Device

This notification for The V.A.C.® device is for labeling change only, to include an additional indication. There have been no significant modifications or design changes to the currently cleared and marketed V.A.C. device, 510(k) No.K992448.

V. Indications for Use

The V.A.C.® System is a powered suction pump system that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound* healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

*The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts.

VI. Clinical Studies to Support Labeling Claims

Since the V.A.C.® System was placed on the market in 1995, KCI has worked through non-KCI clinicians to gather date to establish the safety and effectiveness of the V.A.C. System. V.A.C. units have been used internationally treating well over 20,000 acute and chronic wound patients. Major burn centers have been using V.A.C. therapy to assist with healing burns for several years. We believe the findings of the clinical studies, cases reported in the literature, as well as informal reports by clinicians warrants the additional claim that V.A.C. treatment assists in healing partial-thickness burns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Kinetic Concepts, Inc.
William H. Quirk
Regulatory Affairs Department
P. O. Box 659508
San Antonio, Texas 78265-9508

Re: K021500
Trade/Device Name: Vacuum Assisted Closure (VAC)
Regulation Number: 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: October 7, 2002
Received: October 10, 2002

Dear Mr. Quirk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021500

Device Name: **The V.A.C.® System**

Indications For Use:

The V.A.C.® System is a powered suction pump system that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound* healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

*The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021500